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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,298	08/08/2001	Vincent Bryan	46739/262600	3319

23370 7590 08/12/2003

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EXAMINER

PRIDY, MICHAEL B

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 08/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary	Application No.	Applicant(s)	
	09/924,298	BRYAN ET AL.	
	Examiner	Art Unit	
	Michael B Priddy	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44, 52-54, 56-96, 101-110 and 112-120 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-9, 13-19, 21-44, 69, 75, 76, 85-92, 106-110 and 112-119 is/are allowed.
- 6) ☐ Claim(s) 10-12, 52-54, 56-68, 70-74, 77-80, 82-84, 93-96 and 101-105 is/are rejected.
- 7) ☐ Claim(s) 20 and 81 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12, 111 and 119 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (US 5,674,296). Bryan et al. teach a surgical implant 18 suitable for use in a joint between the surfaces of two bones 12 & 14, comprising: two rigid opposing shells 32 & 34, each having an outer surface 52 & 54 adapted to engage the surfaces 112 & 114 of the bones 12 & 14 of a joint in such a way that movement of the shell relative to the bone surface is resisted by friction between the outer surface and the surface of the bone and each having a tab 72 & 74 extending axially way from the central body; an inner surface 62 & 64 that is smoother than the outer surface 52 & 54; and an edge between the outer surface and the inner surface; a deformable, resilient central body 20 disposed between the inner surfaces 62 & 64 of the shells 32 & 34 comprising an outer surface, at least a portion of which has a shape that compliments and articulates with the shape of the inner surface of one or both rigid opposing shells to allow the inner surface of the rigid opposing shell and the outer surface of the central body to move easily with respect to each other within a constrained range of motion, but to resist such movement outside the constrained range

Art Unit: 3732

of motion; and further comprising a flexible sheath 110 extending between edges of the opposing shells, having an inner surface that, together with the inner surfaces of the rigid shells, defines a cavity containing the central body. Bryan et al. further teach that the central body 20 is comprised of a "relatively stiff annular gasket exterior portion 22 and a relatively supple nuclear central portion 24.

It should be noted that the language "adapted to releasably receive a tool for manipulating, inserting or removing the implant" in lines 1-2 of claim 11 is merely functional and does not explicitly require a tool. It is the belief of the examiner that the elements 72 & 74 are capable of performing the function of receiving a tool.

Claims 52-54 and 56-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Büttner-Janz et al. (US 5,401,269). Büttner-Janz et al. teach an implant comprising a central body 3 encapsulated by two shells 1 & 2, said central body 3 having an upper convex and a lower convex contact surface 6, wherein an upper shoulder 7 extends around a portion of the perimeter of the upper contact surface 6 and a lower shoulder 7 extends around a portion of the perimeter of the lower contact surface 6. Central body may further include a central axial opening 14 therein. Shells 1 & 2 include surfaces roughened by teeth 5.

Claim 74 is rejected under 35 U.S.C. 102(b) as being anticipated by Ray et al. (US 6,123,465). Ray et al. teach a bone joint implant 20 comprising a central body 22 and a lubricant encapsulated within a structure 24 having at least one opening 36 for

Art Unit: 3732

the introduction of the lubricant into the structure. Openings 36 are large enough to allow bodily fluids "lubricants" to interact with hydrogel core 22.

Claims 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Buettner-Janz et al. (US 4,759,766). Buettner-Janz et al. teaches an intervertebral disc endoprosthesis comprising a central body positioned between two shells 21 wherein at least one shell includes an inner surface having a central retaining post 19 extending therefrom and adapted to allow rotation of the shells 21 relative to the central body wherein the retaining post 19 is substantially centrally located on the inner surface and wherein the inner surface is of a shape that articulates with the shape of at least a portion of the central body. It should be noted that the pins 19 and recesses of Buettner-Janz limit maximum mobility of the intervertebral disc endoprosthesis but do not prevent movement entirely.

Claims 80, 83, 84 and 120 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US 5,370,697). Baumgartner teaches an artificial intervertebral disk member comprising a central body 5 positioned between two shells 2 & 3, wherein the shells have edges that include radial stops 16 & 17 extending generally axially from portions thereof and wherein the shells have edges that include tabs 28 extending generally axially from portions thereof. It should be noted that the language "a shoulder" in lines 1-2 of claim 83 does not explicitly require "a shoulder" be present on the central body as this feature has been recited only functionally.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. in view of Walker (US 4,193,139). Büttner-Janz et al. teach a bone joint implant comprising a central body 3 positioned between two shells 1 & 2 each having an inner surface that contacts the central body. Hence Büttner-Janz et al. teach all of the limitations of the present invention except that the inner surfaces of the shells 1 & 2 are machined or polished.

Walker teaches a prosthetic finger joint 10 comprised of a first stemmed component 12; a second stemmed component 14; a bearing pad 16; a bushing 18; and an axle 19. "Arcuate bearing surface 25 is polished smooth, so as to facilitate the pivoting motion of the first component of the joint in use, and also to reduce unnecessary friction in the movement of the joint, thus reducing wear of pad 16." (lines 56-61 of column 3) It would have been obvious to one of ordinary skill in the art at the time of the present invention to polish the inner surfaces of the shells of the implant of Büttner-Janz et al. so as to improve their wear characteristics when articulating with the central body 3.

Claims 66-68, and 70-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. in view of Ducheyne et al. (US 4,990,163).

Art Unit: 3732

Büttner-Janz et al. teach a central body 3 positioned between two shells 1 & 2 having outer surfaces. Therefore Büttner-Janz et al. teach all of the limitations of the present invention except that the outer surface of at least one of the shells is coated to promote bony ingrowth.

Ducheyne et al. teach a method of depositing calcium phosphate ceramics for bone tissue calcification enhancement. This procedure is used to facilitate bony ingrowth when using cementless fixation of permanent implants. The method, as described in lines 19-30 of column 11 and in the first paragraph of column 12, involves the vacuum sintering of a mixture of hydroxyapatite onto titanium. It would have been obvious to one of ordinary skill in the art at the time of the present invention to provide a coating of hydroxyapatite onto the outer surface of the shells of Büttner-Janz et al. so as to enhance bone ingrowth thereinto. Concerning the limitation of claims 70 and 71 requiring the material be of titanium it would have been obvious to one having ordinary skill in the art at the time the invention was made to use whatever material was deemed appropriate for the particular application, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner as applied to claim 80 above, and further in view of the following. Baumgartner discloses the claimed invention except that the radial stop extends a distance of less than about 2.5 mm from the edge. It would have been obvious to one having ordinary skill in the art at the time the invention was made to for the stop of

Art Unit: 3732

whatever dimensions would have been appropriate for the particular application, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233

Claims 93-96 and 101-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Buechel et al. (US 5,868,796). Bryan et al. teach a surgical implant 18 comprising an elastomeric central body 20 positioned between two shells 32 & 34. Bryan et al. therefore teach all of the limitations of the present invention except that the central body 20 is impregnated with a surface hardening or lubricity increasing material.

Buechel et al. teach a biologically inert wear resistant surface 26 on the head 18 of a femoral, stem-type prosthesis. The surface is the result of a titanium nitride coating. "The much smoother characteristics of surfaces subjected to wear that are enabled by the harder coating 26 contribute substantially to wear resistance, abrasion resistance and lubricity. It would have been obvious to one of ordinary skill in the art at the time of the present invention to apply titanium nitride to the bearing surface of the central body 20 of Bryan et al. so as to substantially improve its wear resistance.

Claims 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Waits (US 5,593,445). Bryan et al. teach a bone joint implant comprising a central body 20 positioned between two shells 32 & 34. Therefore, Bryan et al. teaches all of the limitations of the present invention except that the central body has a polymer coating thereon.

Waits teaches a bi-axial prosthetic joint the articulating surfaces of which may be coated with polyurethane or other biocompatible polymeric resins to further reduce friction (col. 11, lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of the present invention to coat the outer surface of the central body of Bryan et al. with polyurethane so as to reduce the friction between the central body and the shells 32 & 34.

Response to Arguments

Applicant's arguments with respect to claims 10-12, 52-54, 56-68, 70-74, 77-84, 93-96 and 101-105, filed 05/22/2003 have been fully considered but have not been found persuasive.

In response to Applicant's arguments with respect to anticipation rejections and the fact that a reference must teach each and every feature of the invention claimed the Examiner responds by stating that in each case of an allegedly improper rejection under 35 U.S.C. 102, Applicant has pointed to a particular feature that is apparently missing from the reference applied. In each of these cases, the Examiner believes the rejection has clearly set presented every element of the claimed invention and indicated what feature of the reference corresponds to each structural feature recited by the claim.

Applicant's arguments relative to all 35 U.S. C. 103(a) rejections are essentially the same and that is that there's no motivation to combine references and that the Examiner has used hindsight reasoning in making the combinations. The motivational statements in each of the rejections under 103(a) were taken from the references

Art Unit: 3732

themselves and in most cases from the modifying or secondary reference. It is therefore the belief of the Examiner that there, in fact, is motivation for making each of the combinations set forth above.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgement on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971).

Allowable Subject Matter

Claims 1-9, 13-19, 21-44, 69, 75, 76, 85-92 and 106-119 are allowed.

Claims 20 and 81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

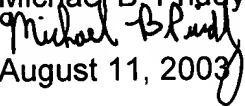
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

Art Unit: 3732

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

August 11, 2003